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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,284	EHRICHT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,25,27,29-37,39-45 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,25,27,29-37,39-45 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 23 May 2008 in which claims 1, 27, 27, 44 were amended to define the cavity as "adapted to amplify and characterize nucleic acids almost simultaneously". The amendments have been thoroughly reviewed and entered.

The previous objections in the Office Action dated 14 December 2007 are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102 and 35 U.S.C. 103(a) are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims1-19, 25, 27, 29-37, 39-45 and 47 are under prosecution.

Claim Interpretation

2. The claims have been amended to define the reaction chamber as "adapted to amplify and characterize nucleic acids almost simultaneously". The instant specification defines this adaptation at page 7, second and third paragraphs. The third paragraph is reproduced below.

> The problem is thereby inventively solved in that a device is provided which is characterized in that a chamber body containing an optically permeable chip having a detection area, and being optically permeable at least in the zone of the detection area of the chip, is sealingly placed on an optically permeable chamber support, so that a sample chamber having a capillary gap is formed between the chamber support and the detection surface of the chip, which is temperature-adjustable and flow-controllable. This

> type of constructions allows reactions to be carried out, which efficiently take place only in determined temperature ranges, and to detect almost simultaneously the reaction products by chip-based experiments.

This defines the reaction chamber the newly claimed adaptation as optically permeable thereby permitting almost simultaneous amplifying and characterizing of the nucleic acids.

The previously examined claims defined the chamber body as having an optically permeable zone and an optically permeable chamber support. Hence, the newly defined reaction chamber, as described in the instant specification, does not further define the device. Therefore, the previous rejections are maintained and made final.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5, 8-15, 17-19, 25, 27, 29-30, 34-36, 39-45, 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999).

Regarding Claim 1, Stapleton et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip having a detection area within an optically permeable zone of detection (Column 14, lines 40-57), the detection area including an array of multiple different nucleic acids immobilization (Column 5, lines 40-44), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), an inlet for liquid introduction (Column 6, lines 10-15) whereby a continuous cavity forms a single reaction chamber adapted to amplify and characterize nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57).

Regarding Claim 2, Stapleton et al disclose the device further comprising a temperature adjustment means connected to the chamber adapted to permit temperature control (e.g. temperature sensor and valves, Column 13, lines 16-25).

Regarding Claim 3, Stapleton et al disclose the device wherein the temperature adjustment means are on the sidewalls of the chamber (Column 13, lines 57-60).

Regarding Claim 4, Stapleton et al disclose the device the detection zone includes detection spots (i.e. probe array) and the temperature adjustment means does not affect the transparency of the chip i.e. on the sidewalls of the chamber (Column 13, lines 57-60 and Column 14, lines 36-57).

Regarding Claim 5, Stapleton et al disclose the device wherein the heating elements comprise micro-structured elements (Column 14, lines 9-17).

Regarding Claim 8, Stapleton disclose the device wherein the chamber support and body consist of optically permeable material e.g. glass (Column 14, lines 40-57).

Regarding Claim 9, Stapleton disclose the device wherein the chamber support consists of thermally conducting material (Column 13, lines 57-60).

Regarding Claim 10, Stapleton disclose the device wherein the chip consists of optically permeable material e.g. glass (Column 14, lines 40-57).

Regarding Claim 11, Stapleton et al disclose the device further comprising an optically permeable conical recess in the detection area (inverted cone #28, Column 9, lines 50-59).

Regarding Claim 12, Stapleton et al disclose the device further comprising spatially separate inlet (#20) and outlet (#30).

Regarding Claim 13, Stapleton et al disclose the device wherein the spatially separate inlet (#20) and outlet (#30) are arranged unilaterally to the chip (Fig. 1) and separated by a gas reservoir (i.e. inflatable valve, Column 13, lines 26-40).

Regarding Claim 14, Stapleton et al disclose the device wherein the chamber is sealingly connected to the support by an adhesive (Column 5, lines 45-54).

Regarding Claim 15, Stapleton et al disclose the device wherein the detection area is configured in spots of immobilized probes i.e. arrayed probes spaced by a few microns (Column 5, lines 40-44).

Regarding Claim 17, Stapleton et al disclose the device wherein the detection area is configured in the form of spots onto which probes are immobilized (i.e. probe array, Column 14, lines 36-43).

Regarding Claim 18, Stapleton et al disclose the device configured for optical detection (Column 14, lines 40-45).

Regarding Claim 19, Stapleton et al disclose the device is adapted to allow various forms of detections via optical and non-optical methods (Column 14, lines 40-54). The instantly recited "by a silver precipitation reaction" does not describe or define a structural component of the device. Because the recitation "by a silver precipitation reaction" does not further define the device, Stapleton anticipates the claimed invention.

Regarding Claim 25, Stapleton et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip having a detection area within an optically permeable zone of detection (Column 14, lines 40-57), the detection area including an array of multiple different nucleic acids immobilization (Column 5, lines 40-44), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), an inlet for liquid introduction (Column 6, lines 10-15) whereby a continuous cavity forms a single reaction chamber adapted to amplify and characterize nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57).

Regarding Claim 27, Stapleton et al disclose the device wherein the optically permeable chip includes a detection area having immobilized probes within a gap (chamber) (Column 5, lines 40-64).

Regarding Claim 29, Stapleton et al disclose the device wherein the detection area is optically permeable (Column 14, lines 40-45).

Regarding Claim 30 Stapleton et al disclose the device wherein the chamber is temperature adjustable and flow controllable (Column 12, line 62-Column 13, line 60 and Column 14, lines 14-23).

Regarding Claim 34, Stapleton et al disclose the device wherein the chamber body includes polycarbonate or polymethylpentene (Column 11, lines 18-20).

Regarding Claim 35, Stapleton et al disclose the device wherein the chamber body includes a sealing surface adapted to releasable connect to the support e.g. adhesive or clamping mechanisms (Column 5, lines 50-54 and Column 12, lines 8-25).

Regarding Claim 36, Stapleton et al disclose the device wherein the nucleic acids include one of DNA or RNA i.e. nucleic acids for the analysis of genes or gene expression, Column 4, lines 25-31).

Regarding Claim 39, Stapleton et al disclose the device wherein the optical detection includes fluorescent detection (Column 14, lines 35-57).

Regarding Claims 40-43, Stapleton et al disclose the device wherein the device is suitable for reactions e.g. amplification, thermocycling, antibody binding, expression analysis, enzymatic reactions, etc. (abstract, Column 4, lines 11-37, Column 15, lines 2-20). The instantly claimed "adapted to perform" does not define or describe structural

elements of the device. Because Stapleton et al specifically teach the structural elements of Claim 1, because Stapleton et al teach various reactions performed within the device, and because the instant claims do not define further structural components of the device, Stapleton et al anticipate the device as claimed.

Regarding Claim 44, Stapleton et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip having a detection area within an optically permeable zone of detection (Column 14, lines 40-57), the detection area including an array of multiple different nucleic acids immobilization (Column 5, lines 40-44), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), an inlet for liquid introduction (Column 6, lines 10-15) whereby a continuous cavity forms a single reaction chamber adapted for reacting and characterizing nucleic acids therein (Column 10, line 1-27 and Column 14, lines 40-57) and further a sample inlet (#20) and outlet (#30) are connected to the single chamber (Fig. 1).

Regarding Claim 45, Stapleton et al disclose the device wherein the gap includes means for reacting the sample (Column 14, line 58-Column 15, line 20).

Regarding Claim 47, Stapleton et al disclose the device wherein the chamber is free of fluid channels to move the nucleic acids to a subsequent chamber (Fig. 1).

Response to Arguments

5. Applicant states that the instant claims are drawn to a device having a continuous cavity adapted for amplifying and characterizing nucleic acids almost

simultaneously. Applicant asserts that Stapleton does not teach a chamber body that includes an optically permeable chip and an array of polynucleotides immobilized on the optically permeable chip.

The argument has been considered but is not found persuasive. As cited in the previous office action, Stapleton specifically teach the optically permeable chip and reaction chamber as claimed. Stapleton teach construction of the chamber body using optically clear plastics wherein the optically clear chamber is affixed to a glass slide forming an optically reaction chamber (Column 11, lines 35-38). Stapleton further teach the chip is printed on (or bonded to) a microscope slide (i.e. optically permeable support) which becomes one of the opposing walls forming the optically permeable chamber (Column 14, lines 36-57). Hence, Stapleton teaches all elements of the device as claimed.

Applicant points to the instant specification and asserts that the claims define chip “held by chamber body 1 thought edge 42 thereof". From this, Applicant asserts that the claims define three distinct elements, which is not taught by Stapleton. The assertions are noted, however, the claims are not so limited as to require a body having an edge for holding the chip as illustrated. Furthermore, while the claim does not require three distinct elements, Stapleton does teach the array bonded to the glass slide thereby providing three elements (Column 14, lines 36-39).

Applicant argues that Stapleton never indicates that the two different functions of thermocycling and hybridizing are performed almost simultaneously. The argument has been considered but is not found persuasive. First, the almost simultaneous

amplifying and characterizing as recited in the claim are recitations of intended use. The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Therefore, the intended use as recited in the claim does not define the device over the device of Stapleton. Second, as stated above in paragraph 2, the instant specification defines the instantly claimed device as "adapted" by means of optically permeable detection zone and support. As cited above, Stapleton teaches these elements. Therefore, Stapleton teaches the device adaptation as defined by the instant specification. Finally, the claims are not limited to almost simultaneous thermocycling and hybridizing. The claims merely define the device for amplifying and characterizing. Hence, the argument is not commensurate in scope with the claims.

Applicant further points to various teachings in Stapleton wherein reactions are serially added to and removed from the working space. The citations are noted, however these teachings do not alter the fact that Stapleton does teach all the structural elements required by the claims.

Applicant's attention is again pointed to Claims 6 and 12 of the Stapleton patent, which are drawn to the device having two opposing walls and materials for "reacting and analyzing components of the biological specimens". Hence, Stapleton clearly teaches all the elements of the claimed invention. The rejections are maintained.

6. Claims 25, 27, 29, 30, 44, 45, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Besemer et al (WO 95/33846, published 14 December 1995).

Regarding Claim 25, Besemer et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip (e.g. glass support, page 6, lines 3-29) having a detection area within an optically permeable zone of detection (e.g. #310, Fig. 3), the detection area including an array of multiple different nucleic acids immobilization (page 7, lines 4-12), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (transparent cover, page 24,lines 19-28), an inlet for liquid introduction (page 6, lines 29-33) whereby a continuous cavity forms a single reaction chamber adapted for reaction (e.g. hybridize) and characterize (e.g. sequence) nucleic acids therein (page 20, lines 23-31).

Regarding Claim 27, Besemer et al disclose the device wherein the optically permeable chip includes a detection area having immobilized probes within a gap (page 24, lines 19-28).

Regarding Claim 29, Besemer et al disclose the device wherein the detection area is optically permeable (page 24, lines 19-28).

Regarding Claim 30 Besemer et al disclose the device wherein the chamber is temperature adjustable and flow controllable (page 13, lines 10-45).

Regarding Claim 44, Besemer et al disclose a device for duplication and characterizing nucleic acids comprising a chamber body containing an optically permeable chip (e.g. glass support, page 6, lines 3-29) having a detection area within

an optically permeable zone of detection (e.g. #310, Fig. 3), the detection area including an array of multiple different nucleic acids immobilization (page 7, lines 4-12), an optically permeable support on which the chamber body is sealingly place to form a continuous cavity enclosing the array (transparent cover, page 24,lines 19-28), an inlet for liquid introduction (page 6, lines 29-33) wherein the device is adapted for reaction (e.g. hybridize) and characterize (e.g. sequence) nucleic acids therein (page 20, lines 23-31) and further a sample inlet and outlet are connected to the single chamber (e.g. Fig. 3, #350/#360)

Regarding Claim 45, Besemer et al disclose the device wherein the gap includes means for reacting the sample (page 20, line 43-page 21, line 4).

Regarding Claim 47, Besemer et al disclose the device wherein the chamber is free of fluid channels to move the nucleic acids to a subsequent chamber (e.g. Fig. 3).

Response to Arguments

7. Applicant asserts that Besemer does not teach a device for both amplifying and characterizing nucleic acids. The argument has been considered but is not found persuasive. Claims 25, 27. 29-30, 44-45 and 47 are drawn to a device adapted for almost simultaneous reacting and characterizing nucleic acid comprising an optically permeable support. Besemer teaches theses elements as defined by the instant specification. The rejection is maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) in view of McBride et al (U.S. Patent No. (6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 6 and 7, Stapleton et al teach the device comprising automated fluidic movement (Column 9, lines 9-36 and Column 14, lines 25-35). However, Stapleton is silent regarding a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple electrodes providing a distribution of magnetic poles (Column 3, lines 34-55). Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode

device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the electrodes of Stapleton et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

Response to Arguments

10. Applicant reiterates the arguments regarding Claim 1 and asserts that McBride does not cure the deficiencies of Stapleton. The argument is not found persuasive based on the above discussion regarding the teaching of Stapleton.

11. Claims 16, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claims 16 and 37, Stapleton et al teach the device wherein the nucleic acids include one of DNA or RNA i.e. nucleic acids for the analysis of genes or gene expression, Column 4, lines 25-31) and wherein the preferred probe arrays are made using the method of Affymetrix (Column 14, lines 46-49). Stapleton does not specifically teach DNA or RNA probes immobilized through spacers.

However, Fodor et al (i.e. Affymetrix and VLSIPS technology) teach their probes are DNA or RNA (Column 5, lines 32-34) and immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Stapleton et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Response to Arguments

12. Applicant reiterates the arguments regarding Claim 1 and asserts that Fodor does not cure the deficiencies of Stapleton. The argument is not found persuasive based on the above discussion regarding the teaching of Stapleton.

13. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) in view of Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claims 31-33, Stapleton et al teach the device comprising resistive heaters/sensor (Column 14, lines 14-17) but is silent regarding the composition of the resistive heaters. However, nickel-chromium thick film resistive heaters and sensors were well known and routinely practiced in the art at the time the claimed invention was

made as taught by Lipshutz et al (Column 24, line 53-Column 25, line 6). Lipshutz et al further teach their resistive heater composition is capable of producing temperatures in excess of 100 degrees without adverse affects. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the resistive heater composition of Lipshutz et al to the resistive heaters of Stapleton. One of ordinary skill in the art would have been motivated to do so based on the preferred use and benefits taught by Lipshutz et al (Column 24, line 53-Column 25, line 6).

Response to Arguments

14. Applicant reiterates the arguments regarding Claim 1 and asserts that Lipshutz does not cure the deficiencies of Stapleton. The argument is not found persuasive based on the above discussion regarding the teaching of Stapleton.

Conclusion

15. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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